

1- Identification of the biological product (or preparation) and of the Company

1.1 – Identification of the biological product or preparation

Biological product: Replication-defective Lentiviral vectors, VSV-g pseudotyped

Identified uses: For research use only. Not for use in diagnostic procedures.

1.2 – Company product identification

VECTALYS SAS
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☎ + 33 (5) 62 26 12 44
✉ vectalys@vectalys.com

1.3 – Emergency phone number

North America:

CDC Center for Disease Control and Prevention: ☎ 911

CDC National Center for Environmental Health & Agency for Toxic Substances and Disease Registry: ☎ + 1 770-488-7100

Europe:

List of national helpdesks - ECHA

France: ORFILA number (INRS): ☎ + 33 (0)1 45 42 59 59

German emergency telephone number ☎ + 49 (0) 231 9071 2971

2- Composition – Information on Ingredients

Biological product:

Viral vector name: rLV-EF1- transgene -WPRE

Type: Lentiviral vector

Promoter: hEF1 (human elongation factor one)

Replicative: NO

LTR: LTR HIV: Δ U3 (deletion) RU5

3- Hazards identification

Pathogenicity of the GMO lentiviruses-derived: the non-replicating vector, derived from HIV, have a low pathogenicity because they do not encode the viral proteins required for viral replication. These are self-inactivating (SIN) vectors because their promoter / enhancer (U3 sequence) is inactivated. These are non-propagative vectors.

Symbol:



Biohazard

Classification: Biohazard of Biosafety level 2 BSL-2

Potential health effects:

<u>Principles routes of Exposure:</u>	Skin cut with accidental exposure to blood, Splashing into eyes, Ingestion
<u>Acute toxicity:</u>	
Eye	May cause irritation
Skin	May be harmful if absorbed through the skin
Inhalation	/
Ingestion	May be harmful if swallowed
<u>Chronic toxicity:</u>	Not available
<u>Environmental hazard:</u>	See section 13 (Disposal of care activities involving infectious risks)

Security phrases:

S20/21: Do not eat, do not drink and not smoke while using.

S24/25: Avoid contact with skin and eyes.

S29/56: Do not empty into drains, dispose of this material and its container at a collection center for hazardous or special waste.

S36/37/39: Wear suitable protective clothing, gloves and protective equipment and eye / face.

4- First Aid measures

Immediately following an exposure incident, (such as needlestick, sharp items, or other percutaneous exposure, non-intact skin exposure, eg. skin with dermatitis) the exposed area shall be thoroughly washed. Mechanically clean contaminated skin, cuts, scratches, or puncture wounds by gently rubbing a povidone iodine solution, such as Betadine® or chlorhexidine disinfectant into the wound (preferably with sterile gauze or a sponge). Allow soaking of the wound for 15 minutes with the disinfectant, and follow by a flushing with copious amounts of water. In the absence of a disinfecting solution, soap and water may be used. In the event of an exposure to the eye, the eye should be irrigated with the laboratory eyewash for at least fifteen (15) minutes.

General advice	An accident/incident investigation form should be initiated and should document the route(s) of exposure, the circumstances under which the exposure incident occurred, the viral vectors titer, description of the transgene and if human blood, fluids, tissues or cells are involved, the identification and documentation of the source individual or material.
Skin contact without lesion caused	Clean affected area with soap and water, then rinse. Decontaminate the affected area with disinfectant adapted and validated
If splashed on mucous membranes or eyes	Flush thoroughly with water or saline solution (if wearing contact lenses, allowing the water to loosen, not wear contact lenses when handling viral vectors)
In the event of puncture or injury:	Clean the injured area of skin with water and soap, then rinse. Decontaminate the affected area with a prolonged bath (at least 5 minutes) using an adapted and validated disinfectant with appropriate spectrum of activity.

5- Fire fighting measures

Not applicable

6- Accidental release measures

Safety personal precautions :

- Use personal protective equipment: see section 8.
- Person to contact: Head of Health and Safety
- Keeping records of incidents.

Environmental precautions :

Use containers with specific "Biohazard" symbol and autoclave the waste, for decontamination: see section 13.

- handling in appropriate containment area: see section 7.
- transport by an approved carrier: see section 14.
- person to contact: Head of Health and Safety.
- keeping register of incidents.

Methods for cleaning up: In case of spills of viral supernatant, soak up with inert absorbent material and decontaminate the area by using an adapted and validated disinfectant with appropriate spectrum of activity.

7- Handling and storage precautions

Advice on safe handling: Handle a biohazardous material under Biosafety Level 2 (BSL-2) containment.

Storage conditions:

- Local: BSL-2 containment area with "Biohazard" symbol
- Tank: -80°C freezers with "Biohazard" symbol
- Conditions: -80°C upon receipt.
- Packaging / containers: storage boxes for freezing tubes with "Biohazard" symbol

8- Exposure controls, personal protection

Exposure control :

<u>Collective protection</u>	BSL-2 containment, BSC-2 Biosafety cabinet-2	
<u>Personal Protective Equipment</u>	Respiratory protection	
	Eye / Face protection	Mask with visor / plastic visors or goggles
	Skin and body protection	Cotton blouse / lab coats
	Hand protection	gloves
<u>Hygiene measures</u>	Good laboratory practices	
<u>Environmental protection</u>	BSL-2 containment	

Mandatory use of gloves and disposable lab coats or designed for handling viral vectors. The gloves are decontaminated before being discarded immediately after handling.

9- Physical and chemical properties

Serum free medium.

Appearance: clear to brown

Physical state: liquid

Odor: none

10- Stability and reactivity

Lentiviral vectors are stable for several years at -80 ° C, 1 year at -20 ° C, a few days at 4°C.

Stability: They are not stable in air or water.

Hazardous Decomposition Products: None under normal use conditions.

11- Toxicological information

Any information available.

12- Ecological information

Degradability: degradation in 15 min at 50 °C.

Known and predicted habitats of the GMO-producing cells (human kidney epithelial cells 293T).

13- Disposal information

Lentiviral vectors are GMOs **risk class C2** and therefore regarded as wastes from care activities involving infectious risks not spread (medical waste).

Regulatory classification: Category 18, Waste from Health care and / or related research.

Residues:

- Solid Waste: pipettes, tubes and culture dishes contaminated
- Liquid Waste: culture supernatant

Packaging:

GMO Class C2 must be placed in appropriate containers to the type of waste:

- Sharps: Sharps
- Autoclavable bags: solid waste in the absence of validated inactivation procedure
- incineration with plastic containers labeled "Biohazard" or inactivated autoclaved solid waste, Sharps
- cans incinerables: liquid waste

Method of disposal of the product and its packaging:

- Decontamination:
 - o Solid Waste in contact with an appropriate and validated disinfectant anti HIV-1 spray.
 - o Liquid waste placed in contact with an appropriate and validated disinfectant anti HIV-1.
 - o needle boxes closed and placed under BSC-2 out in a trash bag closed.
- Autoclave at 121 ° C for 20 minutes in autoclavable bags or containers and incinerate. Wastes that are sterilized in a remote location of the laboratory should be placed in a labeled container, durable and waterproof, which is closed and disinfected externally prior to transport from the laboratory. After autoclaving, the bags are placed in autoclavable plastic containers incinerable labeled "biohazard."
- Store containers and plastic containers incinerated in a specific room, separated from the laboratory and ventilation.
- Management of medical waste by an authorized company collecting waste to be incinerated in approved incinerators. Requires a schedule for monitoring "Disposal of care activities involving infectious risks."

14- Transport information

Number ONU/UN : 3373

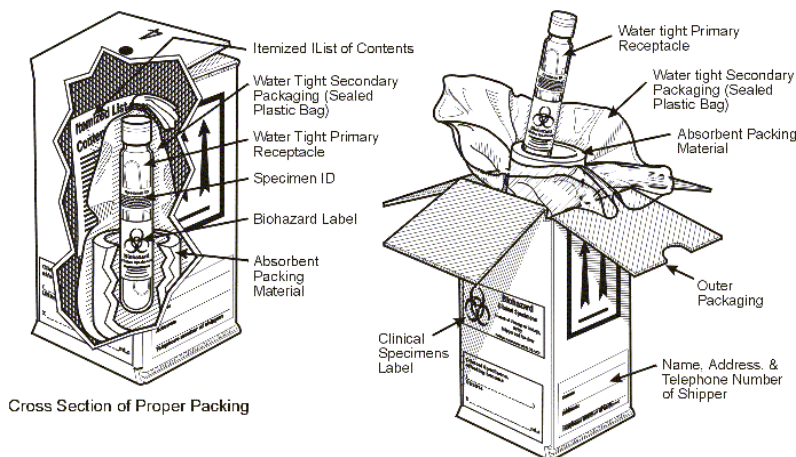
Class: 6.2 if packaged with ice dry

Risk category: Biological substance, Category B

Expedition name: lentiviral vectors (GMO)

Labeling: Class 9 label, including UN1845, and net weight if packaged with dry ice

Packing instruction 650:



Packing and Labeling of Clinical Specimens

1. Packages must be of good quality, strong enough to withstand the rigors of transport
2. Triple packaging consisting of leak proof primary receptacles (for liquid shipments), silt proof primary receptacles (for solid shipments), leak proof secondary packaging, outer packaging of sufficient strength to meet the design type test (1.2 meter drop test)
3. For liquid shipments, primary receptacle or secondary packaging capable of withstanding a 95Kpa internal pressure differential
4. Absorbent material sufficient to absorb the entire contents of the shipment
5. An itemized list of contents (delivery sheet) must be included between the secondary and outer packaging
6. "Biological Substance, Category B" must appear on the package
7. Minimum dimension 100mm
8. See IATA 5.0 p451/452 for the complete document

Labeling: Below are examples of labels required on biological material packages.



IATA Instruction: 650

The sender is responsible for sending even when outsourcing to a transporter

15- Regulatory information

Symbol :



Classification: Biohazard Biosafety level BSL-2

WHO (www.who.int) :

- "Transport des substances infectieuses" 2011
- « Guidance on regulations for the transport of infectious substances » September 2011

16- Other information

Notice to readers:

To the best of our knowledge, the information contained herein is accurate. However, the supplier mentioned above assumes any liability whatsoever in respect to the accuracy or completeness of the information contained in this document. The user should exercise independent judgment as to the hazards based on all sources of information available. All biological products may present unknown hazards and should be used with caution. Although certain hazards are described herein, we can not guarantee that there are none others.